IN THE U.S. PATENT AND TRADEMARK OFFICE

In re application of

Carl Ernest ALEXANDER et al. Conf. 2239

Application No. 10/766,912 Group 1612

Filed January 30, 2004 Examiner Lezah Roberts

PERSONAL CARE COMPOSITIONS WITH PORTABLE PACKS

DECLARATION UNDER RULE 132

Assistant Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

I, Carl Ernest Alexander, hereby declare as follows:

I am one of the inventors of the above-identified U.S. patent application. My relevant background and experience are set forth on the attached CV.

I have read the Official Action mailed October 2, 2009, and I am familiar with the present application.

I hereby declare that...

In relation to the timing of cleaning one's teeth, I was always aware that our patent as filed did not specifically provide a time duration for the cleaning of a person's teeth. I have always intended that a person using my dentifrice beads would take no longer to clean their teeth than they do with toothpaste. It was important that use of our invention does not prolong the procedure. In our instant U.S. patent application the steps involved are listed at lines 317 to 321.

The inherent **"brittle gel"** property of agar, on which our invention relies, causes the active ingredients of the dentifrice to be rapidly released from a bead at the commencement of a tooth cleaning procedure, at the end of a long shelf life. We did state at line 514 that those "*concentrations of agar between about 0.5% and 1.2% would break up easily when in use*", and at lines 122-124 that "*the concentration of agar would allow the semi-solid composition "to break apart and render the at least one active ingredient when disrupted*". Also see for instance line 288, and line 318.

In relation to the Official Action at page 5. My earlier patent (the "secondary reference" WO2002/026078) was the best solution that I could think of at the time. I have always known that the inevitable presence of a capsule would have detracted from the appeal of a single-dose capsule for use as a dentifrice by children. It would also detract from use by adults.

While it is easy to identify a problem such as this, finding a fully user-compatible answer proved to require invention and considerable effort. We have also solved the matter of production costs, which could have been prohibitive, as they most likely would be if a capsule was used in our invention. This invention resulted from my engaging the services of Mr Grayson who is my co-inventor. I agree that it is perhaps remarkable that no prior publication of my above-identified U.S. patent application has been located. Perhaps it is true that the simplest inventions are among the hardest to make.

I note that the Examiner states that it would be obvious to try out existing patents. I note that no other patent making use of the fragmentable nature of agar to quickly release active ingredients while providing a stable, temperature-tolerant storage means was known to us, or has since been discovered.

The cited patents, Grossmith GB 750,126 and Schmidt US 5,354,551 were not considered during our developments. If we had read Grossmith before realizing that agar was to provide the key to solving our problems, we would simply have learnt that there are ways to combine individual gelling agents to make, for example, a tough gel or a viscous solution. Grossmith did not set out to provide a single-dose personal care preparation. Once we realized that agar was the key, we can read in Grossmith (page 1, lines 39-43) that his invention is directed towards abolishing the very

property on which we rely; namely its fragmentability. As for Schmidt, we could not have used it as a guide because the amount of missing information was so extensive that an ordinary person could not fill in the gaps. I have not tried to make a Schmidt film type of dentifrice based on US 5,354,551. My first problem is that the Schmidt patent does not describe how to convert a wet slurry into a dry film, such as at column 2, lines 44-48 or column 3, lines 49-53. The description makes a magical leap over all the necessary details. I cannot determine whether the components have to react together, if heating or cooling is involved, or if there is another, unidentified additive. Although Schmidt does set out to provide a single-dose dentifrice, the idea of a thin film that must dissolve before use does not appear to be consistent with our objective of provide an effective, quickly available, single-dose dentifrice without a capsule. Something that has actually dissolved in the mouth will tend to be swallowed immediately.

The Examiner states at page 5 that it "would have been obvious to one of ordinary skill in the art" to have made coloured bead shapes using the Schmidt patent US 5,354,551, and so create my invention. Schmidt would not provide for varying shapes. I don't know if the Schmidt materials themselves can be coloured, but the market is replete with toothpaste inside packaging made attractive to children, who know that the contents may not be as

attractive. A composition that is attractive to children has to simulate or improve on ordinary toothpaste as far as possible. The accompanying evidence of Mr Silcock states, on the basis of his trials, that it would not be attractive. He describes the mouth feel as "gluggy". Our beads also allow a child to change flavor for example from one use to the next.

Suppose that a Schmidt film is deformed into a bead shape. In order to simulate my invention, it will obviously take a lot longer to dissolve that deformed film at the time of use than if the same amount of material was already in a flattened, film shape.

In any case our invention relies on fragmentation throughout of the brittle gel made from agar, and does not rely on a dissolving process, for a relatively fast release of the active ingredients from the storage medium at the time of use. In user trials, we have learnt that our compositions, which lack the "tackifiers" of ordinary toothpaste such as sodium carboxymethly cellulose, are preferred by many people over ordinary toothpaste.

In relation to the Official Action at page 6.

The Examiner says at page 6 that it "would have been obvious to one of ordinary skill in the art" to have made coloured bead shapes using the Schmidt patent in combination with my earlier

patent and in combination with Grossmith, and so create my invention without any actual inventive process.

My first point in response is that it is quite clear, from the first page of Grossmith, that his two-gel combination is intended to get away from the "brittle gel" property of agar used alone. The patent teaches away from what we have done. A person reading that patent document would not be led to try the instant invention or, if they persisted, they would end up with a viscous material or tough gel that does not break apart. Grossmith-type results might instead turn out like the alginate gel of Vellekoop, US 4,765,984 which is meant to be chewed over a period of time, and does not use a brush.

Second point: As far as specific reference to toothpaste is concerned, Grossmith, at page 3 line 25 within the table "USE", refers to one use of his invention as a "*Stabiliser for tooth pastes*"... . That is the full extent of the disclosure; it is hardly a signpost to a person looking for ideas to provide a single-dose formulation.

Third point: Grossmith offers no benefit to my earlier capsule-type invention, because there is no advantage in putting a stronger gel, as compared to a cream, inside a capsule which is what I described in my original patent, now superseded. Neither is there an advantage to be had by putting a Schmidt film, or

even a bead made by compacting a Schmidt film, inside a capsule. We have now disposed of the capsule completely.

Fourth point: Grossmith and Schmidt are mutually contradictory in that Grossmith sets out to make a viscous tacky but water-containing suspending material provided in pots or in tubes, but Schmidt, so far as I can tell, wants to create a dry yet soluble material provided as flat films. It may be that Grossmith gelling agents are better for use in the Schmidt process than the ones Schmidt actually described; I could not comment because improving Schmidt's films is not my responsibility. But if the user finds he or she has created an unattractive mess supposedly ready to be brushed on the teeth, such an invention will be rejected immediately whether by a child or by an adult.

In relation to the Official Action at page 7.

Although the Examiner says that a particular amount of dentifrice, for use in a single bead, is obvious and not claimable especially given the teachings of Alexander, I believe that it is relatively common to specify an amount, especially where a precisely determined "single dose" is an attribute of the invention and especially where the quantity of dentifrice to be used is combined with a novel vehicle; in this case, a bead of pure agar.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

[[SIGNATURE OF INVENTOR]]

Carl Ernest Alexander

Date 29th January 2010.

Curriculum vitae of Carl Ernest Alexander

I am a Company Director, of joint British and New Zealand nationality. I have always been interested in design and product development. I have designed and developed a number of products and concepts over the years.

The more notable of recent times are:

1. The Boa Strap Wrench. US Design Patent D369,076. It is a form of hand wrench with a rubber strap that has been sold as the Boa Constrictor™. It has been sold in almost every country in the world. Unit sales now exceed 20 million units and are growing. This product is sold in the USA by Sears under their own brand as the Craftsman Strap Wrench. Pirated copies, of which there have been many, might double the total unit sales.

2. The Soda Snap ™ or Canpull ™. It is US Patent Application No. 2004 0163494. This product is a hand tool useful for removing ring pull tops from cans and also breaking the seals on soda cans. This product has also sold in the millions.

I have been developing oral hygiene concepts for some time. My research and development is an ongoing process and presently carried out at Otago University, Dunedin New Zealand, I also have some allied developments in oral hygiene with the Wellington School of Medicine in New Zealand, involving pilot studies on a specialized product advancing oral health for children.

I now devote myself full time to researching and developing these new concepts, as well as market aspects. I am also working on experiments for an effective herbal natural alternative for both cleaning the teeth and general oral health care.

dated 29th January 2010

Carl E. Alexander

Auckland
New Zealand